UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

For Online Publication Only

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MIQUEL CARIAS, VALERIE GENTILE, JANET RAMIREZ, MICHAEL PICONE, EVELYN FLECHA, ZENA MATOS, on behalf of KAILEI MATOS, a minor, JAIME NINO, and HALONA JAFFE, *individually and on behalf all others similarly situated*,

Plaintiffs,

-against-

MONSANTO COMPANY, a Delaware corporation; DOES 1–10, inclusive,

Defendants.

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MEMORANDUM & ORDER
15-CV-3677 (JMA) (GRB)

AZRACK, United States District Judge:

Eight plaintiffs filed this putative class action against defendant Monsanto. Plaintiffs allege that they contracted various maladies because of their use of Monsanto's herbicide Roundup. Plaintiffs raise products liability claims as well as claims under New York General Business Law ("GBL") §§ 349 and 350. Defendant has moved to dismiss the complaint. For the reasons stated below, defendant's motion is granted in part and denied in part. Plaintiffs' claims under the GBL for injunctive relief and plaintiffs' design defect claims are dismissed. Defendant's motion is denied as to plaintiffs' remaining claims.

I. BACKGROUND

Monsanto markets, advertises and distributes Roundup, the world's most popular herbicide. (Second Am. Comp. ("SAC") ¶ 1, ECF No. 17.) The primary ingredient in Roundup is glyphosate. (Id.) The Environmental Protection Agency ("EPA") has approved Roundup and its labeling. (Decl. of Eric Lasker Ex. 1.) The label on Monsanto's Roundup products states that "Glyphosate targets an enzyme found in plants, but not in people or pets" (hereinafter the "plants

not people" statement). (SAC ¶ 141, Ex. A.) The labels on Roundup do not appear to contain any warnings indicating that Roundup may be carcinogenic or may present other serious health risks to humans. (Id. Ex. A; Decl. of Eric Lasker Ex. 1.)

In 2015, despite the EPA's approval of Roundup, the International Agency for Research on Cancer classified glyphosate as "probably carcinogenic to humans." (SAC ¶ 102; see also id. ¶¶ 11, 100–103, 131.) Numerous suits, including the instant action, have been filed against Monsanto in which the plaintiffs allege that they developed cancer from exposure to Roundup.

Here, all eight plaintiffs allege that, in reliance on the "plants not people" statement, they purchased Roundup on "several occasions" over the past four years and "used and/or [were] exposed to the use of Defendant's Roundup products in their intended or reasonably foreseeable manner." (SAC ¶¶ 8, 11, 16, 20, 24, 28, 35, 39, 43, 47, 50, 54, 58, 62; see also id. ¶ 32.) They allege that their "exposure to glyphosate caused" various maladies, including non-Hodgkins lymphoma, pancreatic cancer, renal pelvis cancer, "a pituitary gland tumor," leukemia, "irritable bowel syndrome/leaky gut disease," diabetes, and kidney disease. (Id. ¶¶ 11, 19, 27, 34, 42, 49, 57, 65.)

According to plaintiffs, the statement on Roundup's label that "Glyphosate targets an enzyme found in plants, but not in people or pets" is false. (Id. ¶ 75.) Glyphosate inhibits organisms from producing the enzyme EPSP synthase, which is also known as the shikimate enzyme. (Id. ¶¶ 72–74; Def.'s Br. at 3.) Plaintiffs do not appear to dispute that human cells do not produce EPSP synthase. Rather, plaintiffs allege that EPSP synthase is found in gut bacteria (otherwise known as "gut flora" or "microbiota") that reside in human stomachs and intestines. (Id. ¶¶ 76–81.) The total microbiota found in humans can weigh up to five pounds. (Id. ¶ 81.)

Plaintiffs allege that, because gut bacteria produce EPSP synthase, gut bacteria are vulnerable to being killed off by glyphosate. (Id. ¶ 82.)

Plaintiffs' complaint alleges various common law products liability claims. Plaintiffs also raise claims under GBL §§ 349 and 350, seeking damages and injunctive relief.

Defendant has moved to dismiss plaintiffs' failure-to-warn and GBL claims, arguing that those claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. Defendant also contends that the GBL claims fail, asserting that: (1) the "safe harbor" provisions of the GBL preclude plaintiffs' claims; (2) plaintiffs have failed to plausibly allege a false or misleading statement; (3) GBL claims cannot be premised on personal injuries; and (4) plaintiffs' injuries are unrelated to their purchases of Roundup for their lawns and gardens. Finally, defendant contends that plaintiffs have failed to plausibly allege a design defect claim.

II. DISCUSSION

A. Standard for Motions to Dismiss Under Rule 12(b)(6)

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court takes the complaint's factual allegations to be true and draws all reasonable inferences in the plaintiff's favor. Harris v. Mills, 572 F.3d 66, 71 (2d Cir. 2009). That principle, however, is "inapplicable to legal conclusions." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Moreover, a complaint must plead "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Twombly, 550 U.S. at 556).

In reviewing a motion to dismiss, "the Court is entitled to consider facts alleged in the complaint and documents attached to it or incorporated in it by reference, documents 'integral' to the complaint and relied upon in it, and facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." Heckman v. Town of Hempstead, 568 F. App'x 41, 43 (2d Cir. 2014)

B. Preemption Under FIFRA

Defendant argues that plaintiffs' failure-to-warn and GBL claims are preempted by FIFRA. Specifically, defendant contends that the EPA's decision to approve Roundup's label has preemptive force. Defendant also argues that EPA has concluded in various contexts that, as a factual matter, glyphosate does not pose a chronic health risk to human and is not carcinogenic. According to defendant, those factual findings also have preemptive force.

As explained below, five district courts presiding over similar "Roundup" cases in the Ninth Circuit have rejected the same arguments pressed by defendant here, concluding that none of the EPA's actions cited by defendant preempted the plaintiffs' state-law damages suits. See Hardeman v. Monsanto Co., No. 16-CV-525, 2016 WL 1749680, at *2 (N.D. Cal. Apr. 8, 2016); Giglio v. Monsanto Co., No. 15-CV-2279, 2016 WL 1722859, at *2 (S.D. Cal. Apr. 29, 2016); Sheppard v. Monsanto Co., No. 16-CV-43, 2016 WL 3629074, at *1 (D. Haw. June 29, 2016); Mendoza v. Monsanto Co., No. 16-CV-406, 2016 WL 3648966, at *1 (E.D. Cal. July 8, 2016); Hernandez v. Monsanto Co., 16-CV-1988, 2016 U.S. Dist. LEXIS 126930, (C.D. Cal. July 12, 2016).[1]

The Court generally agrees with the reasoning in these decisions. A few critical points are explored below.

[1] All of these decisions were issued after the briefing was completed in the instant case. Surprisingly, plaintiffs did not bring any of these decisions to the Court's attention. Defendant, of course, is well aware of these decisions.

1. The FIFRA Registration and Enforcement Scheme

FIFRA requires all pesticides to be registered with the Environmental Protection Agency ("EPA") prior to sale or distribution. See 7 U.S.C. §§ 136a(a), 136(b). In determining whether to register a pesticide, the EPA must determine, inter alia, that: (1) "its labeling . . . compl[ies] with the requirements of [FIFRA]"; (2) "it will perform its intended function without unreasonable adverse effects on the environment"; and (3) "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). The EPA will not register (i.e., approve) a pesticide's label if the pesticide is "misbranded." 40 C.F.R. § 152.112(f). Under FIFRA, a pesticide is misbranded if:

> "[the] labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular," 7 U.S.C. § 136(q)(1)(A);
>
> "the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment," 7 U.S.C. § 136(q)(1)(F);
>
> "the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment," 7 U.S.C. § 136(q)(1)(G).

In addition to being responsible for the registration of pesticides under the process outlined above, EPA also has the authority to bring various enforcement actions if it determines that a pesticide is "misbranded," including seeking civil and criminal penalties. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 439 & 439 n.11 (2005) (citing 7 U.S.C. §§ 136k(a), (b), § 136l); 7 U.S.C. § 136l (stating that the EPA can seek civil penalties against any party "who violates any provision of" FIFRA).

FIFRA states that "[i]n no event shall registration of [a pesticide] be construed as a defense for the commission of any offense under this subchapter. 7 U.S.C. § 136a(f)(2). Rather, FIFRA provides that, "[a]s long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter." Id. Hereinafter, the Court refers to these two sentences of 7 U.S.C. § 136(a)(f)(2) as the "prima facie evidence/no defense" provision.

2. FIFRA's Preemption Clause and the Supreme Court's Decision in Bates

FIFRA contains an express preemption provision, which states:

> (a) In general
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
> Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

7 U.S.C. § 136v (emphasis added).

In Bates, 544 U.S. 431, the Supreme Court made it clear that FIFRA's preemption provision does not reach many types of tort claims, such as claims alleging design defects. Id. at 444–45. With respect to failure-to-warn claims, that Supreme Court concluded that although the duty imposed by a common law failure-to warn claim does constitute a state-law labeling "requirement" under 7 U.S.C. § 136v, such a requirement is "not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." Id. at 447. Moreover, the state law does not have to "explicitly incorporate FIFRA's standards as an element of a cause of action in order to survive pre-emption." Id.

However, if a state law requirement imposes any obligations that are broader than FIFRA's requirements, "that state law cause of action would be pre-empted by § 136v(b) to the

extent of that difference." Id. at 453. Bates also stressed that state-law requirements must "be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." Id. "For example, a failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted because it is inconsistent with 40 CFR § 156.64, which specifically assigns these warnings to particular classes of pesticides based on their toxicity." Id.

3. EPA's Approval of the Roundup Label and EPA's Factual Determinations Concerning Glyphosate Do Not Preempt Plaintiffs' Damages Claims

Defendant does not dispute that the general standards that govern products liability claims under New York law and claims under the GBL are equivalent to FIFRA's misbranding standards. Thus, the present discussion assumes that plaintiffs' state law claims do nothing more than allow plaintiffs to pursue a damages remedy if Roundup is misbranded under FIFRA. Nevertheless, defendant contends that the EPA's approval of the Roundup label has preemptive force because, according to defendant, such approval "give[s] content to FIFRA's misbranding standards" and is akin to regulations promulgated by the EPA. Defendant also argues that the EPA has concluded in various contexts that glyphosate is not carcinogenic and that such factual findings also have preemptive force.

i. EPA's Approval of the Roundup Label Does Not Preempt Plaintiffs' Claims.

The Court notes that Bates did not address the precise question before this Court—namely, what is the preemptive effect of EPA's approval of a pesticide label on state-law claims

that allege that the pesticide at issue caused adverse health effects in humans?[2] Nevertheless, at least some passages in Bates seem to suggest that the Supreme Court would reject the argument that EPA's approval of a label preempts failure-to-warn claims concerning risks to human health. Notably, in its preemption analysis, the Supreme Court cited to Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1533 (D.C. Cir. 1984), a decision that permitted a personal injury plaintiff to pursue a failure-to-warn claim, and approvingly quoted the following passage from Ferebee:

> By encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides . . ., a state tort action of the kind under review may aid in the exposure of new dangers associated with pesticides. Successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labelling of their products; alternatively, EPA itself may decide that revised labels are required in light of the new information that has been brought to its attention through common law suits. In addition, the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement."

Bates, 544 U.S. at 450 (quoting Ferebee, 736 F.2d at 1541–42.)

In any event, even assuming that Bates itself is silent on the question at bar, the Court agrees with the persuasive analysis of this issue in Hardeman, which concluded that, in light of the "prima facie evidence/no defense" provision in 7 U.S.C. § 136a(f)(2), there is no "indication that the EPA's approval of Roundup's label ha[s] the force of law" and thus, carries preemptive force. Hardeman, 2016 WL 1749680, at *2; see also Hernandez, 2016 U.S. Dist. LEXIS 126930, at *17. "Because the Supremacy Clause privileges only '[l]aws of the United States,' an agency pronouncement must have the force and effect of federal law to have preemptive force." Reid v.

[2] As defendants point out, Bates remanded the question of whether Texas law and FIFRA were, in fact, equivalent. Moreover, the plaintiffs in Bates were not alleging personal injury claims. They challenged the efficacy, rather than the safety, of the pesticide, alleging that the pesticide damaged their crops. As Bates acknowledged, in approving a pesticide and its label, the EPA does not analyze whether a manufacturer's claims and warnings about the pesticide's efficacy are accurate and sufficient. Instead, the EPA only considers safety risks to humans and the broader environment. Given the divergent approaches taken by the EPA to safety and efficacy, the preemptive effect of the EPA's label approval on tort suits concerning efficacy claims could potentially be different than the preemptive effect of such approval on tort suits involving safety claims.

Johnson & Johnson, 780 F.3d 952, 964 (9th Cir. 2015); see also Fellner v. Tri–Union Seafoods, LLC, 539 F.3d 237, 244–45 (3d Cir. 2008) (explaining that although certain agency actions that do not involve formal rule-making or formal adjudicatory proceedings can still have preemptive effect, such effect should not be accorded to "less formal measures lacking the 'fairness and deliberation' which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law") (emphasis added)); cf. Gen. Motors Corp. v. Abrams, 897 F.2d 34, 39 (2d Cir. 1990) (recognizing that both agency rulemaking and agency adjudication have the binding force of "federal law" and that a consent order that an agency enters into can, depending on the circumstances, also have preemptive effect).

None of the arguments raised by defendant undermine the persuasive analysis in Hardeman.

First, defendant contends that the "no defense" section of the "prima facie evidence/no defense" provision only applies when the EPA approved a "label in the past and . . . subsequent information had surfaced that would cause EPA to impose a new labeling requirement to include a cancer warning." (Def.'s Reply Br. at 7.) Defendants offer no authority for this interpretation, which is at odds with the plain language of the "prima facie evidence/no defense" provision.

Second, contrary to defendant's suggestion, the Court in Bates did not equate the EPA's registration determination (and label approval) to EPA regulations. Bates only acknowledged that EPA regulations have preemptive effect and did not address whether the EPA's approval of a label preempts any tort claims. Cf. Hernandez, 2016 U.S. Dist. LEXIS 126930, at *17–18.

Third, in support of its position, defendant relies on a handful of cases, all of which are either distinguishable or not persuasive. Defendant cites to three cases that appear to conclude, post-Bates, that EPA labeling determinations under FIFRA have preemptive force. See Smith v.

Hartz Mountain Corp., No. 12-CV-662, 2012 WL 5451726, at *1–3 (N.D. Ohio Nov. 7, 2012); Wilgus v. Hartz Mountain Corp., No. 12-CV-86, 2013 WL 653707, at *4–6 (N.D. Ind. Feb. 19, 2013); In re Syngenta AG MIR 162 Corn Litig., 131 F. Supp. 3d 1177, 1208 (D. Kan. 2015). None of the cases are persuasive on this question. The analysis in each case is cursory, and none addresses the "prima facie evidence/no defense" provision of § 136(a)(f)(2) in their discussions of the preemption issue. Notably, in two of these cases, Smith and In re Syngenta, the plaintiffs either disavowed a failure-to-warn to claim or asserted that they were not alleging that the EPA-approved label was insufficient. Nevertheless, the courts in both cases went on to examine those claims and found, in conclusory fashion, that they were preempted. And, the third case, Wilgus, followed Smith without much additional analysis. Moreover, without any explanation, both Smith and Wilgus appear to equate an EPA-approved label with EPA regulations.

Finally, defendant's reliance on another FIFRA case, Fox v. Cheminova, Inc., 387 F. Supp. 2d 160 (E.D.N.Y. 2005), is also misplaced. Because the parties' briefing in Fox failed to adequately address preemption, the court declined to grant summary judgment on that basis. Id. at 167–68. Moreover, the court in Fox had no occasion to address the impact of the "prima facie evidence/no defense" provision because the plaintiffs in Fox pursued a completely different theory of liability than the plaintiffs in the instant case. Id. at 168–69.

For the reasons explained above, EPA's approval of the Roundup label does not preempt plaintiffs' claims.

ii. EPA's Factual Determinations Concerning Glyphosate

Defendant also cites to various documents in which the EPA concluded that glyphosate does not pose cancer risks or other health risks. (Def.'s Br. at 10–12.) Defendant contends that these factual determinations have preemptive force. The five decisions from the Ninth Circuit

cited earlier all rejected the same arguments premised on the same documents. This Court agrees.[3]

Defendant has not shown that an EPA "Fact Sheet," discussing EPA's classification of glyphosate, or an EPA "Desk Statement" have the force of law, and, thus, preemptive effect. See Hardeman, 2016 WL 1749680, at *2. Moreover, "accepting the facts alleged in the [SAC] as true, as the Court must at this stage, the EPA has stated that its classification [of glyphosate] 'should not be interpreted as a definitive conclusion that [glyphosate] will not be a carcinogen'" under any circumstances. Hernandez, 2016 U.S. Dist. LEXIS 126930, at *22; SAC ¶ 109.

The remaining documents cited by defendant are regulations issued by the EPA pursuant to a different statute, the Food Drug and Cosmetics Act ("FDCA"). The "FDCA regulates pesticide residues in the food supply and requires EPA to establish tolerance levels (or exemptions) for the maximum permissible level of pesticide residue on food products." Nat. Res. Def. Council v. EPA, 658 F.3d 200, 202 (2d Cir. 2011) (citing 21 U.S.C. § 346a(a)–(c)). Under the FDCA, a residue tolerance is "safe" if the EPA "determine[s] that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipatory dietary exposures and all other exposures for which there is reliable information." 21 U.S.C. § 346(b)(2)(A)(ii); Nat. Res. Def. Council, 658 F.3d at 202. Defendant does not argue (or offer any authority to indicate) that this provision of the FDCA, standing alone, preempts state law. Rather, defendant suggests that the EPA's factual determinations about glyphosate in regulations promulgated pursuant to the FDCA have preemptive force because, in determining whether to register a pesticide under FIFRA, the EPA must consider the determinations about pesticides that it makes under the FDCA.

[3] Plaintiffs contend that the Court should not consider these documents on a motion to dismiss. The Court assumes that it would be proper to take judicial notice of these documents to establish that EPA made certain determinations and findings.

As noted earlier, in determining whether to register a pesticide, the EPA must determine whether "it will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 136 U.S.C. § 136a(c)(5) (emphasis added). FIFRA defines "unreasonable adverse effects on the environment" to mean "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21 [of the FDCA]." 7 U.S.C. § 136(bb) (emphasis added); see also 40 C.F.R. § 152.112 (setting out various requirements for EPA approval of a pesticide application under FIFRA and stating that "if the intended use of the pesticide results . . . in pesticide residues . . . in or on food or animal feed," EPA will only approve the application if "all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408").

The Court agrees with the decisions in Hernandez and Mendoza, which concluded that the factual determinations made by the EPA in regulations promulgated pursuant to the FDCA do not have preemptive force. As the court in Hernandez persuasively reasoned, "if the EPA's registration decision [under FIFRA] is not preemptive, it follows that the factual findings on which it relied in making that decision also are not preemptive." Id.; see also Mendoza, 2016 WL 3648966.

4. Plaintiffs' Request for Injunctive Relief under the GBL is Preempted by FIFRA

Under both GBL § 349(h) and GBL § 350-e, a plaintiff injured by a violation of those statutes can seek "to enjoin such unlawful act or practice."

Defendant argues that FIFRA preempts plaintiffs' request for injunctive relief under the GBL. The Court agrees. Although plaintiffs' claims for damages under state law are not preempted, plaintiffs' claim for injunctive relief is. See Hardeman, 2016 WL 1749680, at *2 (explaining that "[d]ictating the contents of Roundup's label would usurp the EPA's exclusive authority, under 7 U.S.C. § 136v(b), to approve all pesticide labeling," but allowing plaintiff's claims to proceed because they sought only damages and not injunctive relief); cf. Mirzaie v. Monsanto Co., No. 15-CV-4361, 2016 WL 146421, at *2 (C.D. Cal. Jan. 12, 2016) (finding that plaintiff's requested injunction was preempted by FIFRA because it would require defendant to alter its label).

Similar to the instant suit, the plaintiff in Mirzaie alleged that the "plants not people" statement on Roundup's label violated California's False Advertising Law. Defendant's argument that FIFRA preempts the injunctive relief requested here is premised on the Mirzaie decision. Plaintiffs respond that Mirzaie's reasoning is flawed. As plaintiffs point out, the brief preemption analysis in Mirzaie appears to imply that an EPA-approved label has preemptive force. See Mirzaie, 2016 WL 146421, at *2 ("There can be no dispute that Plaintiffs seek to impose a labeling requirement different or in addition to that required under FIFRA, as the Roundup label to which Plaintiffs object, and which Plaintiffs seek to alter, was approved by [the EPA] in 2008."). To the extent that Mirzaie suggests that the EPA's approval of a label has preemptive force, the Court disagrees for the reasons stated earlier. That said, whatever the merits of Mirzaie's analysis, its ultimate conclusion—that FIFRA preempts courts from ordering a defendant to change a pesticide label—is, for the reasons stated in Hardeman, undoubtedly correct. Because EPA has the exclusive authority to approve changes to Roundup's label, this Court cannot order defendant to alter its labeling in order to remedy a violation of state law.

Accordingly, plaintiffs' claims for injunctive relief under GBL §§ 349 and 350 are dismissed.

C. Defendant's Other Challenges to Plaintiffs' GBL Claims

1. The GBL Safe Harbors

Defendant argues that plaintiffs' claims under GBL §§ 349 and 350 are barred by the safe harbor provisions of those statutes. GBL § 349(d) states that:

> In any such action it shall be a complete defense that the act or practice is . . . subject to and complies with the rules and regulations of, and the statutes administered by, the federal trade commission or any . . . agency of the United States as such rules, regulations or statutes are interpreted by the federal trade commission or such . . . agency or the federal courts.

GBL § 350-d states that:

> In any such action it shall be a complete defense that the advertisement is subject to and complies with the rules and regulations of, and the statutes administered by the Federal Trade Commission or any official department, division, commission or agency of the state of New York.

Defendant argues that the EPA's approval of the Roundup label satisfies the safe harbor provisions of both statutes. In support, defendant cites to cases finding that the Food and Drug Administration's approval of certain items, such as over-the-counter-drugs, are sufficient to qualify for the safe harbor. See, e.g., Am. Home Prod. Corp. v. Johnson & Johnson, 672 F. Supp. 135, 144–45 (S.D.N.Y. 1987). Defendant, however, has not indicated that the regulatory schemes at issue in those cases included any provisions similar to FIFRA's "prima facie evidence/no defense" provision. In light of that provision, the Court fails to see why EPA's approval of the Roundup label is conclusive on the question of whether the label complies with FIFRA and, thus, falls within the GBL safe harbor provisions. Cf. Singleton v. Fifth Generation, Inc., No. 15-CV-474, 2016 WL 406295, at *8 (N.D.N.Y. Jan. 12, 2016) (denying motion to dismiss based on GBL safe harbor where the United States Alcohol and Tobacco Tax and Trade Bureau approved the alcohol label at issue and reasoning that, inter alia, the Bureau informed

applicants that such approvals do not relieve an applicant from "liability for violations of the Federal Alcohol Administrative Act . . ., which itself prohibits false and misleading labeling"); In re Frito-Lay N. Am., Inc. All Nat. Litig., No. 12-MD-2413, 2013 WL 4647512, at *22 (E.D.N.Y. Aug. 29, 2013) (denying motion to dismiss and reasoning that, inter alia, "it is not clear that FDA's [non-binding] guidance on 'natural' labeling is a 'rule or regulation' within the meaning of §§ 349(d) and 350–d"). Given that FIFRA's "prima facie evidence/no defense" provision does not have the force of law for purposes of preemption, it would seem somewhat anomalous to, nevertheless, find that the EPA's approval of the Roundup label is conclusive for purposes of the GBL safe harbors. Notably, defendant does not cite to any cases that interpret GBL § 349(d)'s phrase "as such rules, regulations or statutes are interpreted by the . . . agency" to cover agency actions analogous to EPA's approval of the Roundup label here.

Defendant also argues that it qualifies for the GBL safe harbor provisions because the New York State Department of Environmental Conservation ("DEC") has also approved the Roundup label. In support, defendant cites to a webpage that includes images of Roundup labels and references, without elaboration, a DEC "registration process." However, neither the website nor defendant's papers mention the statute or regulations pursuant to which the DEC approves such labels. Absent such basic information, the Court cannot conclude that the GBL safe harbors apply here. More importantly, even assuming that the DEC did approve the Roundup labels pursuant to a process under New York state law, plaintiffs' claims under GBL § 349 would still survive because, unlike GBL § 350-e, which also references state statues and agencies, GBL § 349's safe harbor provision only refers to federal statutes and agencies. See Singleton v. Fifth Generation, Inc., No. 15-CV-474, 2016 WL 406295, at *4 (N.D.N.Y. Jan. 12, 2016).

2. Plaintiffs Have Plausibly Pled that the "Plants Not People" Statement is False or Misleading

Plaintiffs' GBL claims are premised on their allegation that the following statement on Roundup's label is false: "Glyphosate targets an enzyme found in plants, but not in people or pets." Plaintiffs claim that this statement is literally false because the enzyme EPSP synthase is, in fact, found in the gut bacteria of humans. Plaintiffs also allege that this statement is "inherently misleading because it creates the impression that glyphosate has no affect [sic] on people or pets, when in reality, it directly affects both people and pets—by killing-off beneficial gut bacteria." (SAC ¶ 145.)

Defendants argue that plaintiffs have failed to plausibly allege that this statement is false or objectively misleading.

To establish a prima facie case under GBL § 349, the plaintiff must show that "defendant is engaging in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof." Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 N.Y.2d 20, 25 (1995). The New York Court of Appeals has adopted an objective definition of "deceptive acts and practices," which requires that the representations or omissions at issue are "likely to mislead a reasonable consumer acting reasonably under the circumstances." Id. at 26; see also Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015). In appropriate situations, a "court may make this determination as a matter of law," but "usually such a determination is a question of fact." Goldemberg v. Johnson & Johnson Consumer Companies, Inc., 8 F. Supp. 3d 467, 478 (S.D.N.Y. 2014); see Kacocha v. Nestle Purina Petcare Co., No. 15-CV-5489, 2016 WL 4367991, at *14–16 (S.D.N.Y. Aug. 12, 2016) (surveying decisions deciding motions to dismiss where GBL § 349 claims challenged representations concerning consumer products).

Defendants cannot dispute that the label's statement that the enzyme at issue is "found in plants, but not in people" is, at least on one reading, literally false. Instead, defendant argues that plaintiffs' interpretation of this statement rests on a "strained parsing of the word 'in,'" and that "[p]laintiffs cannot establish that the use of the word 'in' would deceive a reasonable consumer acting reasonably under the circumstances." (Def.'s Br. at 18.)

Contrary to defendant's argument, the Court cannot conclude, at this time, that plaintiffs' interpretation of this statement is implausible. Notably, defendant does not point to a single case granting a motion to dismiss where the statement at issue was literally false or the statement at issue was even remotely similar to one at bar.

What defendant is really challenging here is the notion that Roundup affects gut bacteria in a manner that is any way detrimental to human health. Defendant vigorously contends that Roundup does not have such an effect, citing various scientific articles and statements from government agencies. The Court doubts that it is proper to take judicial notice of the facts and conclusions in those documents. Even assuming it could, the Court cannot disregard the contrary allegations in plaintiffs' complaint on a motion to dismiss, (see SAC ¶¶ 82–84.) Of course, if defendants are correct, then they will have a strong argument that the "plants not people" statement is not material. However, given the factual allegations in the complaint, these questions are premature and cannot be resolved on a motion to dismiss.[5]

Defendant also argues that the "plants not people" statement is not false or misleading because federal and state regulators have made similar statements in various scientific reports. Although the Court can presumably take judicial notice that federal and state regulators have, in

[5] Defendant's papers never squarely argue that the allegedly false portion of the "plants not people" statement is immaterial. Rather, as made clear in its reply brief, defendant takes the position that the "legal question before the Court . . . is whether the EPA-approved statement on the label regarding humans and pets is false." (Def.'s Reply Br. 9 (emphasis added).)

fact, made such statements, the Court fails to see why such statements would conclusively establish, as matter of law, that the "plants not people" statement is not false or misleading.

3. Plaintiffs Have Alleged a Cognizable Injury Under the GBL

Plaintiffs contend that they have adequately alleged injuries under the GBL because they suffered personal injuries due to their exposure to Roundup. Defendant challenges plaintiffs' allegations of injury on two grounds.

First, defendant notes that, according to the complaint, plaintiffs were exposed to glyphosate by ingesting glyphosate on agricultural crops. Defendant contends that such exposures are insufficient to allege an injury under the GBL because such exposures are not related to plaintiffs' purchases of the Roundup consumer products that are at issue in their GBL claims. In response, plaintiffs point out that the complaint also alleges that the plaintiffs were exposed to the Roundup products they purchased. Defendant's reply brief does not pursue this argument further, and none of defendant's papers cite any authority on this point. Given that complicated questions of causation are normally not decided on a motion to dismiss, defendant's two-sentence-long argument on this issue does not convince the Court that dismissal is warranted here.

Second, defendant argues that the personal injuries alleged by plaintiff do not qualify as actionable harms under the GBL. Surprisingly, there appears to be scant authority on this precise question. The Court notes that defendant's opening brief devotes less than a page to addressing this rather substantial question of New York law.

Both GBL § 349(h) and § 350-e state that "any person who has been injured by reason of any violation of [the statute] may bring . . . an action to recover [his or her] actual damages." (Emphasis added.)

After considering the arguments raised by the parties on this issue, the Court concludes that, in light of the plain language of GBL §§ 349 and 350, and the various statements from the New York Court of Appeals outlined below, the personal injuries alleged by plaintiffs constitute cognizable injuries under those statutes. See Small v. Lorillard Tobacco Co., 94 N.Y.2d 43, 56 (1999) (holding plaintiffs' claims that they would not have purchased cigarettes absent defendant's deceptive practices were not, standing alone, cognizable injuries under GBL § 349, but implying that plaintiffs may have had viable claims if they had sought "recovery for injury to their health as a result of their ensuing addiction"); Karlin v. IVF Am., Inc., 93 N.Y.2d 282, 294 (1999) (allowing plaintiffs who alleged that in-vitro fertilization clinic "engaged in fraudulent and misleading conduct by disseminating false success rates and misrepresenting health risks" to pursue both a GBL § 349 claim and a claim under New York's informed consent statute); Oswego, 85 N.Y.2d at 26 (stating, in a case not involving personal injuries, that "a plaintiff seeking compensatory damages must show that the defendant engaged in a material deceptive act or practice that caused actual, although not necessarily pecuniary, harm" (emphasis added)).

The strongest case cited in defendant's opening brief is Rice v. Kawasaki Heavy Indus., Ltd., No. 07-CV-4031, 2008 WL 4646184, at *1 (E.D.N.Y. Oct. 17, 2008). In Rice, the plaintiff, who bought a motorcycle in New York and was injured in New Jersey, alleged a products liability claim under the New Jersey Products Liability Act as well as a claim under GBL § 349. The court held that the GBL § 349 claim was "subsumed" by the New Jersey Products Liability Act, reasoning that New Jersey courts had reached the same conclusion with respect to similar claims under New Jersey's consumer protection statute. Id. at 9. The facts of Rice are distinguishable. Here, plaintiffs' product liability claims all arise under New York common law. Thus, the Court is not faced with the question of how to address the conflicting statutes of two

different states. Moreover, the rationale of Rice is not persuasive when applied to the circumstances of the instant suit. In contrast to New Jersey, New York does not have a comprehensive products liability statute. Accordingly, it is not clear how the New Jersey decisions cited by Rice, which interpret two potentially conflicting New Jersey statutes, can shed much light either on the intent of the New York State Legislature in enacting GBL § 349 or on the proper interpretation of that statute.

Defendant also cites, for the first time in its reply brief, to a line of federal cases which state that a "loss [under GBL § 349] must be independent of the loss caused by the alleged breach of contract." Spagnola v. Chubb, 574 F.3d 64 (2009). Defendant contends that these cases stand for the proposition that GBL §§ 349 and 350 were not intended to provide duplicative recoveries for injuries recoverable under other existing legal doctrines. The Court is hesitant to read Spagnola as broadly as defendant suggests. First, the Second Circuit's cursory discussion of this issue in Spagnola does not even mention the purported policy rationale that defendant claims animates this line of authority. Second, in Orlander v. Staples, Inc., 802 F.3d 289 (2d Cir. 2015), the Second Circuit read Spagnola narrowly and appears to have limited the scope of Spagnola's sweeping conclusion that "loss [under GBL § 349] must be independent of the loss caused by the alleged breach of contract."[6] In light of the above, the Court does not find Spagnola and it progeny to be persuasive on the issue before this Court.

Although the Court is skeptical that GBL §§ 349 and 350 should apply to personal injury claims, which have traditionally been pursued through product liability suits under New York

[6] In Orlander, the Second Circuit held that the plaintiff sufficiently pled a cognizable injury by alleging "a monetary loss stemming from the deceptive practice and the Defendant's failure to deliver contracted-for services." Id. at 302. The court distinguished Spagnola, characterizing it merely as a suit where "plaintiffs alleged damages in the amount of the purchase price of their contracts, but failed to allege that defendants had denied them the services for which they contracted." Id. at 301–02 (emphasis in original).

common law, defendant has not persuaded the Court at this time. The Court's conclusion on this question (and the other close questions that this case raises under the GBL) are tentative—and the Court may revisit them based on fuller briefing (and a more complete record) at a subsequent stage of the litigation. A number of reasons counsel in favor of such an approach. First, plaintiffs' common law failure-to-warn claims are already proceeding to discovery and it does not appear that the GBL claims will involve much, if any, additional discovery. Second, the instant litigation may very well turn on discrete factual questions. As such, it is premature for this Court to make definitive—and perhaps ultimately unnecessary—pronouncements concerning unsettled questions of New York law.[7]

For the reasons outlined above, the Court declines to dismiss plaintiffs' claims for failing to allege injuries that are cognizable under GBL §§ 349 and 350.

Finally, the Court notes two other points. One, under GBL §§ 349 and 350, prevailing parties may receive attorney's fees. Such fees awards are discretionary. Although the question of fees is clearly not before the Court at this time, it seems doubtful that a discretionary award of fees would ever be appropriate when, as here, the plaintiffs have suffered substantial and high-value personal injuries and allege product liability-type claims under the guise of the GBL. The instant suit is unlike most GBL § 349 claims, which involve statutory damages or minimal actual damages, and where the prospect of an attorney's fees award may be necessary to attract competent counsel.

[7] For example, defendant vigorously asserts that plaintiffs will not be able to prove causation for either their common law or GBL claims. And, causation for the GBL claims appears to be a particularly difficult hurdle as plaintiffs will presumably have to prove that their injuries were caused by the specific Roundup products that they purchased and used even though the plaintiffs were also exposed to glyphosate through numerous other sources—a point noted in plaintiffs' own complaint.

Two, the Court acknowledges that rulings on a motion to dismiss can have particular salience in putative class actions. Because of the nature of the injuries alleged by the named plaintiffs here, the Court has grave doubts that class treatment will be appropriate in this suit.

E. Design Defect Claim

"To state a claim for defective design under New York strict products liability law, a plaintiff must allege that: '(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury.'" S.F. v. Archer Daniels Midland Co., 594 F. App'x 11, 12 (2d Cir. 2014) (quoting Lewis v. Abbott Labs., No. 08-CV-7480, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009)

Defendant argues that plaintiffs have failed to plausibly allege a design defect claim because plaintiffs have failed to allege that it was feasible to design Roundup in a safer manner and have not alleged a safer alternative design. A number of courts have dismissed design defect claims for such infirmities. See, e.g., S.F., 594 F. App'x at 12; DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 622 (S.D.N.Y. 2012). Plaintiffs' only response to this argument is that their design defect claims are not preempted by FIFRA. Although plaintiffs are correct about preemption, plaintiffs never address defendant's argument that they have failed to plausibly plead a design defect claim. Plaintiffs' design defect claims are pled in conclusory fashion and nothing in the complaint plausibly suggests the feasibility of a safer alternative design for Roundup. Accordingly, plaintiff's design defect claim is dismissed.

III. CONCLUSION

For the reasons set forth above, defendant's motion to dismiss is granted as to plaintiffs' design defect claim and request for injunctive relief under GBL §§ 349 and 350. Defendant's motion is denied as to plaintiff's remaining claims.

SO ORDERED.

Date: September 30, 2016
Central Islip, New York

/s/ (JMA)
Joan M. Azrack
United States District Judge